National Cancer Institute (NCI)
Knowledge Acquisition Session Report

Session Date: May 26, 1998 **Session Time:** 3:00 P.M.

Session Topic: IDB Access to Information

Knowledge Analysts: Jennifer Brush, ScenPro, Inc. (Lead); Meg Gronvall, Oracle

Organization: Investigational Drug Branch (IDB), CTEP, NCI

Session Location: NCI

Type of Session:

_____ Interview _____ Task Analysis _____ Scenario Analysis
_____ Concept Analysis _____ Observation __X__ Structured Interview
_____ Other:

Documentation: Knowledge Acquisition Session Report

General Topic Area

Clinical Data Review / Information Resources

Session Goals

- Prioritize the list of IDB Investigator tasks
- Obtain a detailed understanding of the format, content, and method of delivery for all information used by the IDB in the review of clinical trial data.
- Obtain a detailed understanding of the ADR reporting process (from the IDB perspective)

Report Summary

The following document was generated using information obtained in a Knowledge Acquisition session held on May 26, 1998, with experts from the Investigational Drug Branch (IDB) of the National Cancer Institute (NCI). Topics covered included:

- IDB Investigator prioritization of their tasks
- Information resources for clinical data review (including all databases, reports, their format, content and method of delivery to IDB)
- The ADR Reporting process

Prioritization of Investigator Tasks:

#1 Patient Safety
#2 Get agents to trial
#3 Review data

Review of clinical data:

IDB Investigators are reviewing the following information on Phase I reports:

- pt accrual occurring at a reasonable rate
- dose level
- toxicity
- ADRs
- efficacy

Note: Michelle Christian is currently overseeing the revision of Phase I study designs

Information Access

The IDB uses information retrieved from many databases. The bulk of this information is provided in paper reports. Some of the information is not in an easily accessible format. It was suggested that IDB meet with outside contractors to determine the most useful data set and method of presentation/delivery for IDB use. The ability to manipulate the data to meet their needs is an important issue with IDB.

The databases include:

- Theradex for Phase I clinical trial study data (medium accessibility) (Contact: Joanne Moore)
- PIO provides reports from the investigator (paper format) including:
  - Phase I data - comes from Theradex every two weeks in paper format (we are obtaining a sample of this)
  - Phase II data – is received in the form of 1/4ly CDUS reports
  - Protocols - received via CDUS
  - Phase III data - comes from TRI; includes
    - d.o.b.
    - gender
    - ethnicity
    - insurance
    - zip code
    - diagnosis
    - institution code
    - (note: toxicology summary reports for Phase III data are received biannually)
- Cooperative Group Study Info (being replaced by CDUS)
  - Includes Phase II study data (toxicity, accrual all they are required to report)
  - Each coop group has their own data collection/storage system (not standardized)
- ADR database contains LOI database / disease matrix grid. A system (NAIRS) is being developed PI's to report ADRs to NCI. Currently – by the time an Investigator sees the

ADR in the database, it is too late. Usually they receive notification of an ADR via fax, phone or e-mail before the information is input into the database.

- TRI has PAYDIRT system which contains
  - annual report status
  - clinical brochure status
  - log of drug company meetings
  - studies
  - drug
  - disease
  - David Johnson is contact
- EMMES (?) – is a dose escalation database for Phase I & II
- DTP
- RAB has a database of contacts & correspondence (letter types) (when IDB needs correspondence sent out to the investigators, etc., it is sent through RAB
- TASCON contains 2 different mailing lists & one large master list

Note: might want to talk to one of the Information Specialists in IDB (each Investigator has an info specialist)

Adverse Drug Reaction (ADR)

An Investigator is required to submit Adverse Drug Reaction (ADR) within 72 hours to 10 days of the event occurrence. The Investigator submits the ADR to the ADR Coordinator who performs a minimal extraction on the data, creating another report. This report is put in a folder with a tracking label and is given to the IDB Drug Monitor. The Drug Monitor reviews the information (list of toxicities and what caused them) and decides whether or not there is enough information. If the information provided is adequate, a recommendation is made (based on the study, trial phase & type of event). A report is generated (typed & edited multiple times). This is formally submitted to the FDA with the annual report. If the information is inadequate, a list of questions is generated, sent to the ADR Coordinator who reviews the questions. The questions are then forwarded to the Investigator through the Cooperative Group (if applicable). The Investigator provides answers to the questions to the NCI.

AER Review Process